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DRDC Toronto guidelines for compensation of subjects participating in research studies

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Defence R&D Canada
Technical Memorandum
DRDC Toronto TM 2008-138
September 2008

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Abstract

DRDC Toronto is the Agency's research centre that provides guidance, innovation and knowledge about the human's response to the complex and stressful environments that impact CF members in preparation for, during and following humanitarian, peace-keeping and warfighting operations. The Agency has invested in DRDC Toronto to ensure that we can simulate and study these responses with human experimentation conducted by our scientists during in-house laboratory or field experimentation. Central to this capability is the need to recruit subjects, both military and civilian, that are willing to experience certain degrees of stress that are beyond what they would experience during their normal day, and/or that are willing to commit the time for participation that enables the study to be completed in an appropriate time-frame. New consolidated guidelines were needed to establish consistent and transparent procedures for generating rates of compensation that would still enable free and informed consent to be obtained according to Tri-Council Policy guidelines. The new guidelines are intended to be applicable for all studies involving human subjects at DRDC Toronto and perhaps could be extended, in principle, across the Agency. The report includes the rationale behind the development of these new guidelines together with examples of how to use the spreadsheet that will be available for all scientific and technical staff to apply to their studies.

Résumé

RDDC Toronto est le centre de recherche de l'Agence qui conseille, fournit les innovations et assure la gestion des données pour tout ce qui touche la réponse humaine aux situations complexes et intenses qui ont des répercussions sur les membres des FC lors de la préparation, de l'exécution ou à la suite de leurs opérations d'aide humanitaire, de maintien de la paix ou de combat. L'Agence a investi dans RDDC Toronto afin de s'assurer que nous pouvons simuler et étudier ces réponses dans le cadre d'expérimentations menées par nos scientifiques, que ce soit sur le terrain ou dans nos laboratoires. Il est essentiel pour cette organisation de pouvoir recruter des sujets — militaires et civils — qui acceptent de subir des niveaux de stress supérieurs à ceux qu'ils vivraient au cours d'une journée normale et/ou de les encourager à donner de leur temps pour permettre la conduite de ces études dans un cadre temporel adéquat. De nouvelles lignes de conduite unifiées étaient nécessaires pour élaborer des procédures cohérentes et transparentes qui permettraient d'établir des taux de rémunération qui nous donneraient toujours la possibilité d'obtenir un consentement libre et informé, conformément aux directives de l'Énoncé de politique des trois Conseils. Ces nouvelles lignes de conduite doivent pouvoir être utilisées dans le cadre de toutes les études de RDDC Toronto faisant appel à des sujets humains et pourraient, en principe, être utilisées dans toutes les études de l'Agence. Le présent rapport comprend les explications justifiant l'élaboration de ces nouvelles lignes de conduite et donne également des exemples d'utilisation de la feuille de calcul. Celle-ci pourra être utilisée par tout le personnel scientifique et technique dans le cadre de ses études.

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Executive summary

DRDC guidelines for compensation of subjects participating in research studies

Matthew Duncan, David Eaton, Tonya Hendriks, Allan Keefe, Tom M. McLellan, Robert D. Michas and Megan M. Thompson; DRDC Toronto TM 2008-138; Defence R&D Canada – Toronto.

Introduction or background: DRDC Toronto is the Agency's research centre that provides guidance, innovation and knowledge about the human's response to the complex and stressful environments that impact CF members in preparation for, during and following humanitarian, peace-keeping and warfighting operations. The Agency has invested in DRDC Toronto to ensure that we can simulate and study these responses with human experimentation conducted by our scientists during in-house laboratory or field experimentation. Central to this capability is the need to recruit subjects, both military and civilian, that are willing to experience certain degrees of stress that are beyond what they would experience during their normal day, and/or that are willing to commit the time for participation that enables the study to be completed in an appropriate time-frame. New consolidated guidelines were needed to establish consistent and transparent procedures for generating rates of compensation that would still enable free and informed consent to be obtained according to Tri-Council Policy guidelines.

Method: Under the governance of the Director General and through oversight and guidance from the Chief Scientist, a seven-member committee of scientists and technical professionals representing the different research sections within DRDC Toronto was formed for the purpose of creating new guidelines. It was critical that these new guidelines would not only provide consistent and transparent procedures for generating rates of compensation but also they must enable free and informed consent to be obtained in accordance with the Tri-Council Policy statements that govern the ethics of research involving human subjects. The committee met 4 times from January through April 2008 and assigned different tasks to team members for each meeting.

Results: The new guidelines considered compensation for both the stress and discomfort of the study together with the commitment of time made by the subject during their participation. One of the outcomes involved the development of a spreadsheet that will enable investigators to clearly define rates of compensation for a given experiment. The completed spreadsheet will require Section Head approval and will be required, together with the document approval form and subject information package, to be submitted to the Human Research Ethics Committee for their consideration during the review of the protocol.

Significance and Future Plans: These new rates of compensation can be consistently applied to all studies involving human subjects at DRDC Toronto and, in principle, across the Agency and can be easily updated to include new stressors or adjustments to the hourly rate for the subject's time.

Sommaire

Lignes directrices de RDDC concernant la rémunération des sujets participant à des études de recherche

Matthew Duncan, David Eaton, Tonya Hendriks, Allan Keefe, Tom M. McLellan, Robert D. Michas et Megan M. Thompson; Équipe de RDDC Toronto 2008-138; R et D pour la défense Canada – Toronto.

Introduction ou contexte : RDDC Toronto est le centre de recherche de l'Agence qui conseille, fournit les innovations et assure la gestion des données pour tout ce qui touche la réponse humaine aux situations complexes et intenses qui ont des répercussions sur les membres des FC lors de la préparation, de l'exécution ou à la suite de leurs opérations d'aide humanitaire, de maintien de la paix ou de combat. L'Agence a investi dans RDDC Toronto afin de s'assurer que nous pouvons simuler et étudier ces réponses dans le cadre d'expérimentations menées par nos scientifiques, que ce soit sur le terrain ou dans nos laboratoires. Il est essentiel pour cette organisation de pouvoir recruter des sujets — militaires et civils — qui acceptent de subir des niveaux de stress supérieurs à ceux qu'ils vivraient au cours d'une journée normale et/ou de les encourager à donner de leur temps pour permettre la conduite de ces études dans un cadre temporel adéquat. De nouvelles lignes de conduite unifiées étaient nécessaires pour élaborer des procédures cohérentes et transparentes qui permettraient d'établir des taux de rémunération qui nous donneraient toujours la possibilité d'obtenir un consentement libre et informé, conformément aux directives de l'Énoncé de politique des trois Conseils.

Méthode : Un comité de sept scientifiques et techniciens professionnels représentant les différentes sections de recherche de RDDC Toronto a été formé. Ce comité relève du Directeur général; le Scientifique en chef en assure quant à lui la supervision et l'encadrement. Le but de ce comité était d'élaborer de nouvelles lignes de conduite. Ces nouvelles lignes de conduite devaient non seulement définir des procédures cohérentes et transparentes en ce qui concerne l'établissement de taux de rémunération, mais il était essentiel qu'elles permettent aussi d'obtenir un consentement libre et éclairé, conformément à L'Énoncé de politique des trois Conseil qui régit l'éthique de la recherche avec des êtres humains. Le comité s'est réuni à quatre occasions entre janvier et avril 2008 et différentes tâches ont été attribuées aux membres de l'équipe pour chaque réunion.

Résultats : Ces nouvelles lignes directrices cherchent à établir une rémunération tenant compte du stress et des désagréments liés à l'étude, ainsi que du temps que le sujet a consacré à l'étude dans le cadre de sa participation. Un des objectifs visait la mise au point d'une feuille de calcul qui permettra aux experts de définir clairement les taux de rémunération pour une expérience donnée. Une fois remplie, la feuille de calcul devra recevoir l'approbation du chef de section. Elle devra aussi être présentée, accompagnée du formulaire d'approbation ainsi que des renseignements relatifs aux sujets, au Comité d'éthique en matière d'étude sur des sujets humains afin d'être examinée durant la révision du protocole.

Portée et recherches futures : Ces nouveaux taux de rémunération peuvent être utilisés de façon systématique dans toutes les études de RDDC Toronto qui font appel à des sujets humains et, en principe, à toutes les études de l'Agence. Ces taux peuvent facilement être mis à

jour afin d'inclure de nouveaux facteurs de stress ou des modifications au taux horaire du sujet pour son temps.

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1 Background

Defence Research and Development Canada (DRDC), and in particular DRDC Toronto, conducts research that requires human volunteers on a regular basis. As part of the oversight process for the conduct of these experiments, the DRDC Human Research Ethics Committee (HREC) requires the submission and review of all experimental protocols prior to providing ethics approval permitting the initiation of subject recruitment and eventual data collection. The HREC follows guidelines and policies established in 2001 by Canada's Tri-Council, which is comprised of membership from the Canadian Institute of Health Research (CIHR), the Natural Sciences Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC). The Tri-Council produced a policy statement entitled "*Ethical Conduct for Research Involving Human Subjects*". All scientists and technical professionals are encouraged to visit the Tri-Council Policy website to read this document (www.pre.ethics.gc.ca). Section 2 of that document highlights fundamental and important issues related to obtaining free and voluntary consent from volunteers. Article 2.2 states that free and informed consent must be voluntarily given, without manipulation, undue influence or coercion. Part D article 2.4 of section 2, which deals with informing potential subjects, states in Table 1 that additional information on any costs, payments, reimbursement for expenses or compensation for injury are to be provided to the volunteers as part of the process of obtaining free and voluntary consent.

DRDC Toronto has been providing compensation to volunteers for the stress and discomfort of experimental protocols for a long time. However, the first formal set of guidelines that categorized experimental procedures and conditions on a scale of stress levels from 0 to 5 was developed in 1992 by what was then the Biosciences Division¹. These stress levels were converted to rates of compensation based on Treasury Board guidelines that clearly established limits for experimental stress allowance to Canadian Forces (CF) members in accordance with the Queen's Regulations and Orders, now covered by Defence Administrative Orders and Directives (DAOD) 5061-1² and the Compensation Benefits and Instructions (CBI) 205.48³. A few years later in 1995 another set of compensation guidelines was produced by what was then the Command Group⁴ to assist with prescribing rates of compensation for volunteers participating in psychology experiments that involved metrics and stress different from those defined by the Biosciences Division.

DAOD 5061-1 clearly states that CF members are entitled to an allowance that indemnifies them for the stress and discomfort of their participation in an experiment but makes no reference to a similar allowance for DND civilian employees. In fact, there are no Treasury Board guidelines that describe a similar allowance for civilian government employees who volunteer to participate in an experiment. Historically, since volunteers for DRDC Toronto experiments were sometimes comprised of CF members, government civilian employees and non-government civilians, the limits set by CBI 205.48 for CF members were applied to all volunteers. Yet, DAOD 5061-1 clearly states that CF members are considered to be on duty and that civilian DND employees are

¹ K.N. Ackles, Stress Allowance for DND Experimental Subjects, Memorandum 7200-2 (BIO), December 1992.

² www.admfincs.forces.gc.ca/admfincs/subjects/daod/5061/1_e.asp

³ www.forces.gc.ca/dgcb/cbi/engraph/cbi_chapter-205_e.asp?sidesection=6§ion=3

⁴ R.A. Pigeau, Command Group's Guide to Stress Compensation for Human Subjects, 1995.

considered to be at work. Thus, during their participation in an experiment they are being compensated for both the stress of the study and their time since they continue to receive their salary while they are involved as a subject. This is not the current situation for civilian non-government volunteers.

The experimental protocols that are used at DRDC Toronto today involve integrative designs that overlap the physiological and psychological paradigms of previous years. It was evident that disparities in rates of compensation could develop when applying both sets of the old guidelines to these new integrative protocols. As such, there is a need to develop one set of guidelines that is consistent and oversees the compensation to volunteers for their stress and discomfort. In addition, the complexity and invasiveness of our methodology has expanded and the guidelines developed back in the early 1990's are insufficient to characterize the extent of the stress that may be imposed on our volunteer's today. Finally, there is a need to define rates of compensation for government and non-government civilian volunteers that are defensible in the absence of Treasury Board guidelines.

In January 2008, under the direction of the Chief Scientist DRDC Toronto, a committee comprised of representatives from the different research sections was formed with the following objectives:

1. To formulate one consolidated guideline for compensation of stress that is consistent throughout DRDC Toronto and could be applied throughout the Agency.
2. To consider options for methods of compensation for the subject's commitment of time.
3. To develop defensible guidelines for all volunteers whether they are CF members, civilian government employees or civilian non-government employees.

These objectives were to be accomplished while remaining cognizant of the importance of obtaining free and voluntary consent without undue influence or coercion.

2 Our Approach

The committee met four times from January through April 2008 and assigned different tasks to team members for each meeting. Discussions that ensued led to the consensus agreement surrounding the approach for compensation that is presented in the report that follows. One of the outcomes from our approach involved the development of a spreadsheet that will enable investigators to clearly define rates of compensation for a given experiment. The completed spreadsheet will require Section Head approval and will be required, together with the document approval form and subject information package, to be submitted to the HREC for their consideration during the review of the protocol.

2.1 Step 1 – Establishing Boundaries or Limits of Compensation

One of the committee's initial tasks was to canvas national and international colleagues in academic and government institutions to seek boundaries or limits to levels of compensation that are considered acceptable practice elsewhere. Not surprisingly the boundaries were quite large, ranging from no compensation to rates of compensation that could reach as high as \$400 for a single invasive procedure performed in a clinical environment. Some foreign government research establishments relied heavily on military volunteers and provided no compensation for their time since they were considered to be on duty. However, at one government institution military volunteers were provided a monthly stress allowance for their participation. Thus, these practices are similar to our Treasury Board guidelines and CBI 205.48 and DAOD 5061-1.

Academic institutions within Canada that received grants from the Tri-Council (CIHR, NSERC or SSHRC) typically provided compensation that was structured according to the stress of the experiment and the time required for the subject to participate in the study. Again, rates of compensation varied substantially but could exceed the equivalent of \$25/hour for experiments that were considered quite stressful such as immersion in cold water. Consistent for all of the academic and government research institutions was their requirement for Institute Review Board (IRB) approval of their proposals, which included approval of the intended rates of compensation. At no time were the boundaries presented above considered coercive for obtaining informed consent by an IRB reviewing the protocol.

2.2 Structuring a Basis for Payment

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans does not require experimental subjects to be paid, but it does put conditions on the payment of subjects in terms of the amount. Specifically, the following statement is taken from Section 1, Part C1⁵:

⁵ The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Section 1, Sub-section C1

“Above the threshold of minimal risk, the research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective subjects. There is a similar threshold regarding undue or excessive offers of benefit. As an offer of payment in relation to research participation exceeds the normal range of benefits open to the research subject, it is increasingly likely to amount to an undue incentive for participation.”

The Tri-Council Policy statement also describes in Section 2, Part D1⁶ the information that should be included in the consent form in order that a research ethics board can ascertain whether “the development of a payment structure for research participation might place undue pressure on research subjects either to join or remain within a research project”.

National Defence falls under Schedule 1 of the Financial Administration Act (FAA) along with 20 other federal departments. Since DRDC is a Special Operating Agency under National Defence, no payment shall be made unless a person authorized by the Minister of National Defence certifies that the work has been performed according to the contract or in the case of any other payment, that the payee is eligible for or entitled to the payment.⁷

Since a contractual arrangement would not be consistent with the volunteer nature of informed consent, this type of payment structure would be construed as unethical by the Tri-Council. Therefore, any payment to experimental subjects requires certification by the Minister’s authorized person that “the payee is eligible for or entitled to the payment.”

In an experiment there are three possible categories for payment:

- a. a reimbursement for expenses incurred to participate as a volunteer. These may include travel, meals, accommodation, incidentals, child care, and others;
- b. an honorarium for participation related to the stress imposed on the subject and their commitment of time; and
- c. a claim in the event of an accident or injury.

The eligibility for payment reimbursement of costs and claims for injury or accident are covered by the Treasury Board Secretariat’s (TBS) Volunteers Policy⁸, which permits reimbursement for expenses incurred and “protects volunteers against financial and other risks.”

Paying a subject for the discomfort and stress associated with an experiment and their commitment of time for their participation is not covered by the TBS Volunteer Policy. An alternative payment option is the honorarium, which is most often paid to volunteers to government boards and committees. As of 2003, the Contract Policy was updated to exclude honoraria. The Contract Policy defines an honorarium payment as:

“Not one made under a contractual arrangement; rather it is a gratuitous payment as distinguished from compensation for service or hire, and the recipient, if not

⁶ Ibid, Section 2, Sub-section D1.

⁷ FAA, Part III, Article 34.

⁸ http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/vp-pb/vp-pb_e.asp

paid [the honorarium], cannot sue in a Court of Law. Accordingly, the Contracting policy does not govern honoraria.”⁹

In the context of our human-based research studies within DRDC, we wish to compensate our subjects as a way to say thank you for their participation. The definition of an honorarium above is consistent with this philosophy. Thus, the experimental volunteer would still come under the Volunteer Policy and would be covered for costs and injury/accidents but could still be paid an honorarium.

Guidance on honoraria

A draft TBS policy¹⁰ from 2001 sets out restrictions on honoraria.

“An institution’s managers should also take into account the need for equity in determining the amount of an honorarium. The payment should be consistent with the amounts an institution normally pays for similar services and/or with the payments typically made for such services in other institutions of the Government of Canada.”

As discussed in section 2.1, boundaries for establishing limits for rates of compensation were quite large. However, it is important to reiterate that all of these rates were reviewed at other institutions by an IRB that was governed by Tri-Council policy and none of these review boards considered the rates to be coercive.

The same draft policy provides general guidance (for 2001) for honoraria amounts and tax implications:

- Public servants and individuals whose participation is integral to their job duties or role in the organization are normally not paid an honorarium. [*see below*]
- Honoraria generally range between \$200 and \$500 per day, but are not to exceed \$1000 per month. [*The ability to apply a daily rate is supported by Health Canada.¹¹*]
- Amounts larger than \$200 per day normally require justification.
- Honorarium payments exceeding \$500 per year are taxable benefits and the department will issue a T4-A.
- The recipient is required to provide a Social Insurance Number or goods and services tax registration number or business registration number prior to receiving payment for the issuance of the T4-A.

Members of the Public Service may receive an honorarium¹² if:

⁹ http://www.tbs-sct.gc.ca/pubs_pol/dcgpubs/Contracting/contractingpol_4_e.asp

¹⁰ http://www.iog.ca/projects/tbs_consultation_policy.pdf

¹¹ http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/sci-com/anti-infect/sacait_tor_ccstai_att_e.html

- there is no apparent, potential or real conflict of interest between their official duties and the outside activity;
- the work/activity for which they would be receiving an honorarium is an outside activity conducted on their own time; (they cannot be paid an honorarium if the work is part of their official duties and done during working hours, for which they are already receiving a salary);
- the outside activity must be conducted in a manner that will not call into question their capacity to perform their official duties;
- they cannot directly or indirectly use government property of any kind for anything other than officially approved activities;
- they cannot knowingly take advantage of, or benefit from, information that is obtained in the course of their official duties and responsibilities and that is not generally available to the public, for use in their outside activities.

Health Canada and Environment Canada procedures for paying honoraria require that a participant in an event receive a letter of invitation stating the services that are expected, the amount of the honorarium, the expenses that will be covered, and how these will be reimbursed. After participating an invoice detailing the honorarium and expenses incurred (if applicable), with original receipts attached and a copy of the invitation letter must be submitted to Finance for payment. This is very analogous to our current procedure. Prior to participating in an experiment, the subject reads and signs the consent form which could be considered an analog to the invitation letter. The consent form includes the activities the subject will participate in and remuneration provided (it should also include expenses that will be covered). After participating, a general allowance claim is prepared on the subject's behalf and sent to Finance for payment.

2.3 Compensation for Stress through the Consolidation of Previous Guidelines

Rather than try to create entirely new guidelines for the different stressors that are part of the research designs within DRDC Toronto, we have consolidated and updated the previous guidelines developed by the Biosciences Division and Command Group into a single package, which is shown in Annex A.

2.4 Compensation for Time

The following considerations would apply to non-government civilians or public servants participating in an experiment on their own time. As of 1998, the Federal Government downloaded to the provinces the responsibility to set a minimum wage. Between now and 2010, the Ontario Government has legislated that the current minimum wage will increase to \$10 per hour. To be consistent with that target, that rate was selected as the initial construct for determining compensation for the subject's commitment of their personal time to participate in

¹² http://www.psagency-agencefp.gc.ca/veobve/question_week/question_week_e.asp#18

the study. If and when the provincial minimum wage exceeds \$10 per hour then our rates of compensation would be adjusted accordingly.

A somewhat arbitrary ceiling was adopted to establish a maximum compensation that might be received for one day. In theory, a subject who was required to participate for an entire day (e.g., a sleep deprivation study) could receive \$240 for the compensation of time. It was decided that this total would be capped at 85% or \$204 using the current rate of compensation for time of \$10 per hour. Once again, if the provincial minimum wage increases to above \$10 per hour then so would the daily maximum. The daily ceiling, however, would remain titrated to 85% of the theoretical maximum that would be paid for a 24-hour time commitment by the subject.

To be consistent with placing a ceiling on the daily maximum, weekly and monthly maximums were also titrated accordingly. The weekly ceiling was capped at 3 times the daily maximum, or currently \$612, using the rationale that few studies involved a commitment by the subject of more than 3 days during any given week. The monthly maximum was also capped at 3 times the weekly, or 9 times the daily, maximum. This monthly ceiling thus equates to \$1836 at this time. It is important to note that our weeks are defined as 7-day cycles and our months are defined as 30-day cycles that start with the volunteer's first day of participation in the experiment. Thus the week and month are not set by the calendar but instead are defined by the duration of the experiment.

2.5 Combining Compensation for both Stress and Time

It was the consensus of the committee that the new guidelines needed to provide for an appropriate blend of compensation for both the stress and discomfort of the experiment as well as the subject's commitment of time. For example, compensation for participation in an experiment that was very stressful and involved numerous invasive procedures but was of very short duration should be properly weighted to reflect the stress. Conversely, compensation for an experiment that involved minimal stress but required many hours of the subject's time should reflect that latter commitment.

In order to create this appropriated balance, the committee decided that individual stressors, shown in Annex A, that were applicable to a given experimental protocol would be additive. Thus, if a particular experimental day involved light exercise at 40°C while wearing protective clothing for an hour or more (stress level 5), while measuring core temperature with a rectal probe (stress level 1) and obtaining blood samples through a venous catheter (stress level 2), then these stress levels would be additive. Each stress level was assigned an equivalent weighting of 5% of the daily maximum. Thus, for the example above, subjects would receive 40% of the daily maximum (\$81.60) as compensation for stress. If the experiment lasted 3 hours then non-government civilians and public servants participating on their own time would receive an additional \$30 for their commitment of time or a total compensation of \$121.60. Several other examples of these calculations are presented in Annex B.

When selecting stressors to include in the summation of total stress for an experiment, keep in mind that each instance of a unique class of psychological stressor is to be represented as a single instance of that stressor. For example, a battery of 5 separate cognitive tasks followed by an interview administrated together in a single session does not translate into 6 instances of level 1 stress for a total sum of 6 stress levels. The multiple instances of the cognitive task are to be

considered as a single instance of the stressor so the total stress level would be 2 (all cognitive tasks + interview). Note that this applies only to the psychological stressors.

It must be emphasized that the above discussion applies only to non-government civilians and public servants participating in an experiment on their own time. For CF members and for public servants participating during work hours, CBI 205.48 clearly stipulates the maximum allowance, currently set at \$60.61, which can be received for stress. These individuals would receive no further compensation for time since they are considered to be on duty or at work, respectively, while they are participating.

It should be apparent that CF members and public servants participating during work hours would receive exactly the same stress allowance. Also, non-government civilians and public servants participating on their own time would also receive exactly the same total compensation for stress and their commitment of time. However, between these 2 groups of participants (CF members and public servants participating during work hours versus non-government civilians and public servants participating on their own time) compensation for stress may be different due to the ceiling imposed by CBI 205.48 and the total compensation may be different due to the different way that the subject's time is compensated.

3 The Spreadsheet

One of the objectives of the committee was to develop a spreadsheet that could be used easily by all staff during the preparation, planning and execution phases of an experiment. Completion of the spreadsheet would become a necessary component of the Section Head and HREC approval processes prior to beginning the actual subject recruitment phase of the study. This spreadsheet and user instructions can be found at the following link

http://corpranet.toronto.drdc-rddc.gc.ca/corpranet/rsrch_exp/stress_remun_guidelines.

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4 Summary and Recommendations

This report describes the basis for a new set of guidelines to govern the compensation of volunteer subjects participating in DRDC Toronto experimentation. The guidelines can be applied universally to cover CF members, civilian government employees as well as non-government civilian volunteers. To assist in the implementation of these guidelines, it is recommended that Section Heads;

- i. provide internal guidance and oversight to rates of compensation calculated for their section protocols,
- ii. sign a completed spreadsheet that details rates of compensation to be included with the protocol approval form and subject information package sent to the HREC for review, and
- iii. be responsible for the management of their civilian government employee's participation in experiments.

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Annex A Consolidated Stress Guidelines

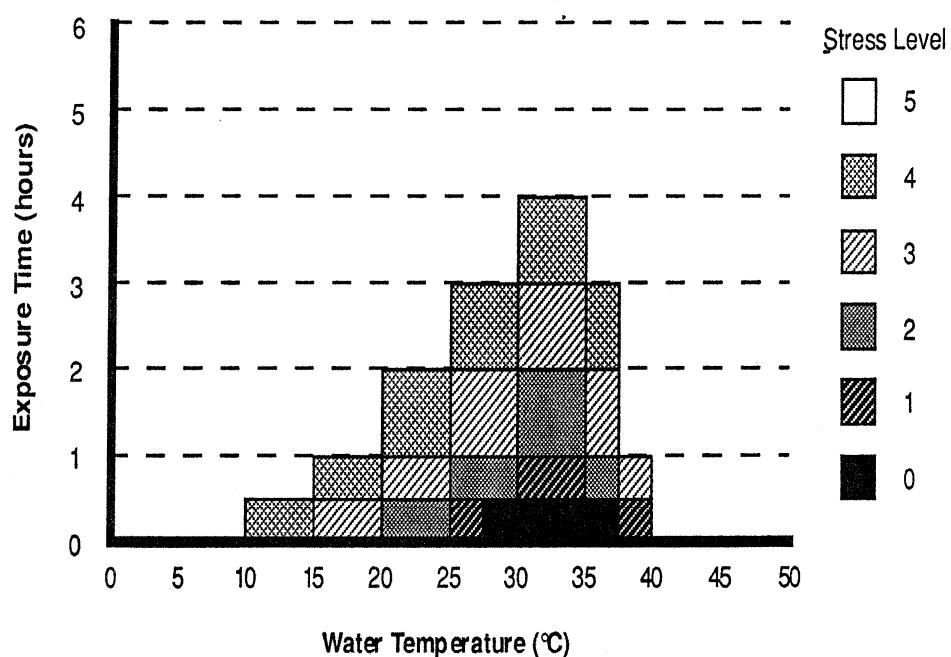
I. Thermal Environmental Stress

Exposure to environmental conditions outside the normal thermal comfort range imposes an environmental thermal stress on the body. In addition, duration of exposure to this environment increases the degree of discomfort felt by the subject. A series of charts have been developed which attempt to relate the degree of discomfort and stress to clothing, experimental procedures, ambient conditions, and duration of the test.

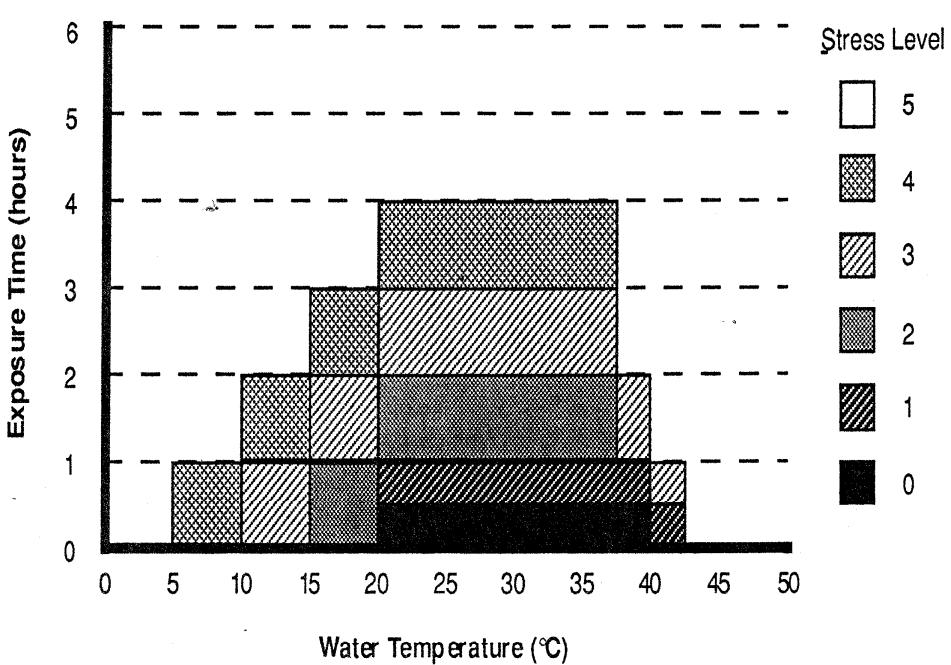
Explanation of Terms Used in Thermal Environmental Stress Charts

- Nude: This refers to the wearing of minimal clothing, such as shorts or a swimsuit, with or without a T-shirt. The clothing is worn only for modesty. For water immersion studies only, “dressed” (see below) is the same as “nude”.
- Dressed: This refers to the wearing of a broad range of clothing. It could include as little as summer combat fatigues (or street clothes such as jeans and shirt, or jogging suit), through complete flight gear for aircrew, to a full chemical defence ensemble plus flight gear or army webbing. The clothing will generally add some insulation to the body, which could be beneficial in the cold but detrimental in the heat, but it is not intended to protect against environmental stress. Arctic clothing is excluded from this category and is dealt with specifically below.
- Protected: This refers to the use of clothing and/or equipment that is specifically designed to protect the user against the thermal effects of the environment. In the case of water immersion studies, the protective garment would be some form of wet or dry immersion suit, or even a hot water suit. For air exposures, protective garments would be cooling suits for heat exposures, or heavily insulated items (Arctic parkas, ski suits, sleeping bags, etc) for cold exposures. The term does not generally refer to chemical defence protective clothing, since such clothing adds thermal stress to the body as opposed to protecting against thermal stress.
- Partial Immersion: This refers to water immersion of a portion of the body such as a finger, hand, arm, foot, or leg. In general, the remainder of the body is in a thermoneutral ambient environment.
- Light Work: This refers to a level of activity that can be sustained for extended periods of time without undue fatigue, or a comparable metabolic rate that may arise from shivering. In general, the additional heat produced in the body will provide some protection against minor cold stress, and will reduce tolerance to heat exposure slightly.
- Heavy Work: This refers to a level of activity that cannot be sustained for a long period of time without fatigue. The heat production in the body can extend tolerance to cold somewhat (think of cross country skiing and the clothing worn for that activity), but will severely curtail tolerance to heat exposure.
- Note that there are an infinite number of combinations of ambient temperature, clothing, and work rate that the charts attempt to cover. Judgment will be required in unusual cases in order to arrive at a fair assessment of the degree of stress. In that sense, the charts are not fixed references, but merely guidelines for the experimenter.

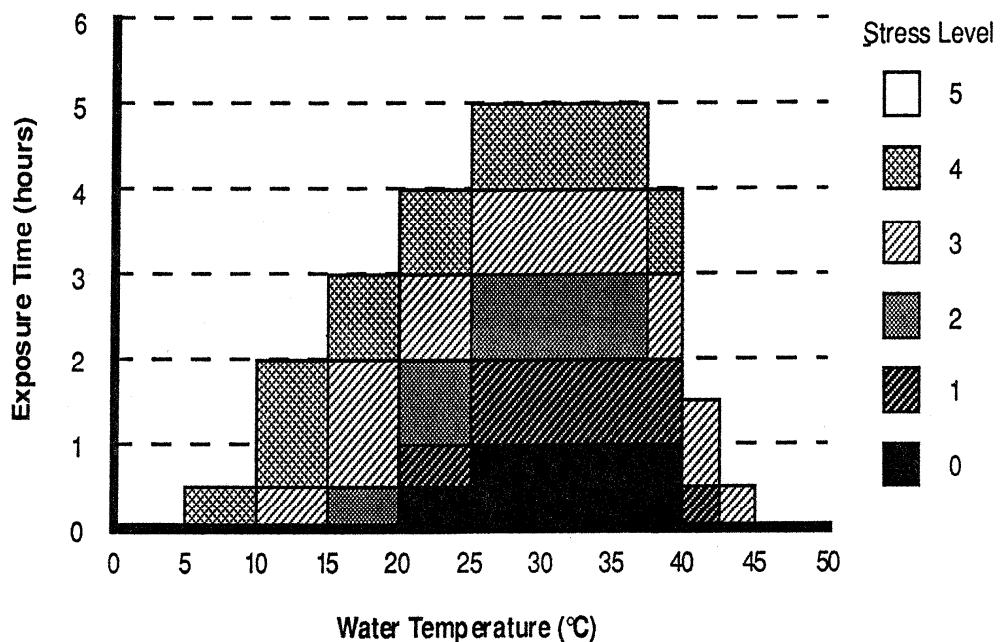
Water; Nude



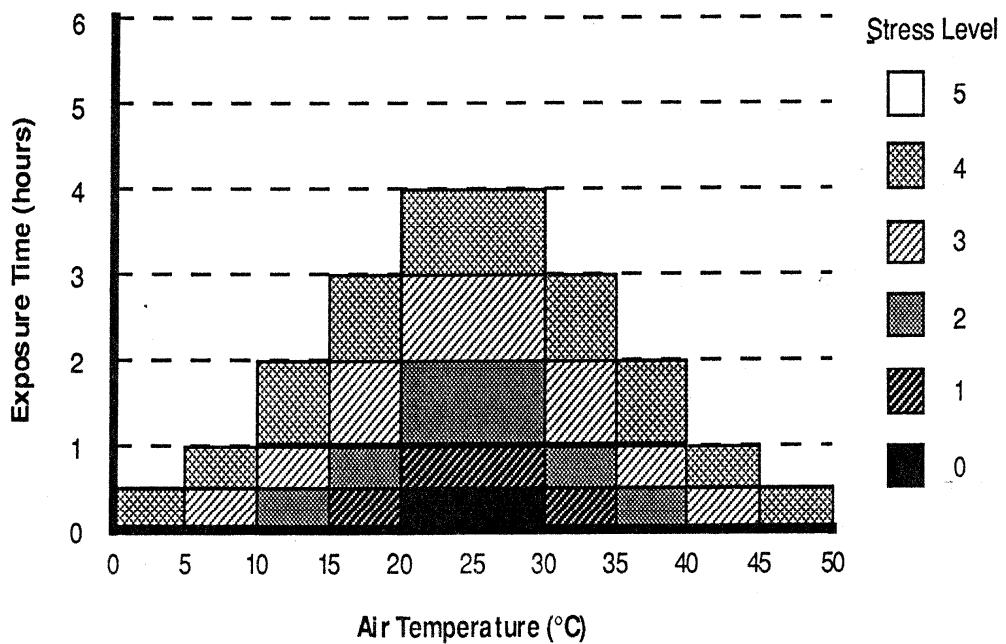
Water; Protected



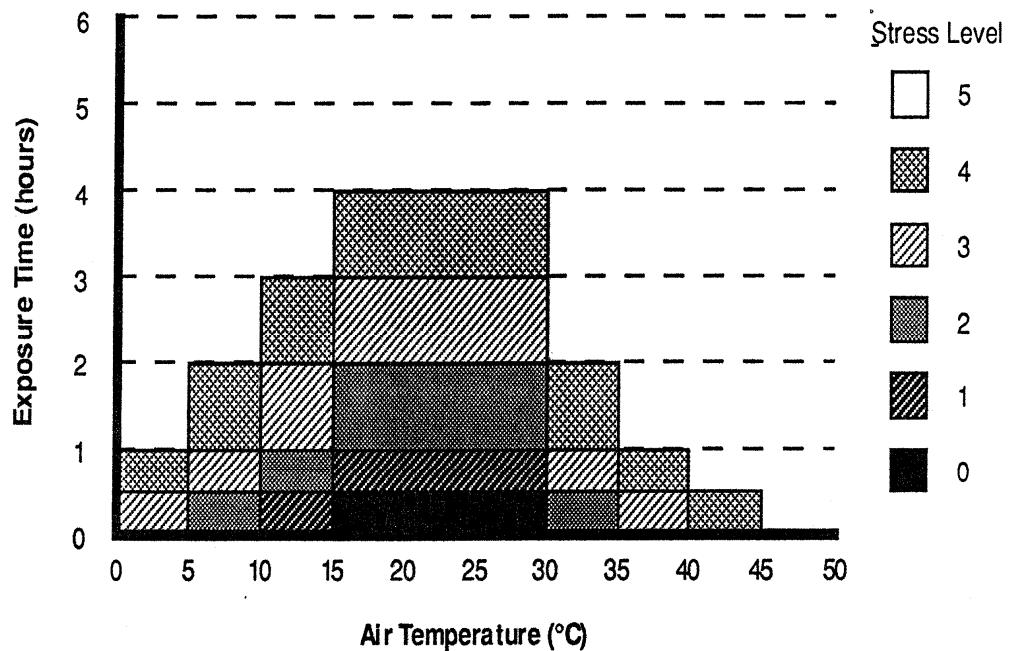
Water; Partial Immersion



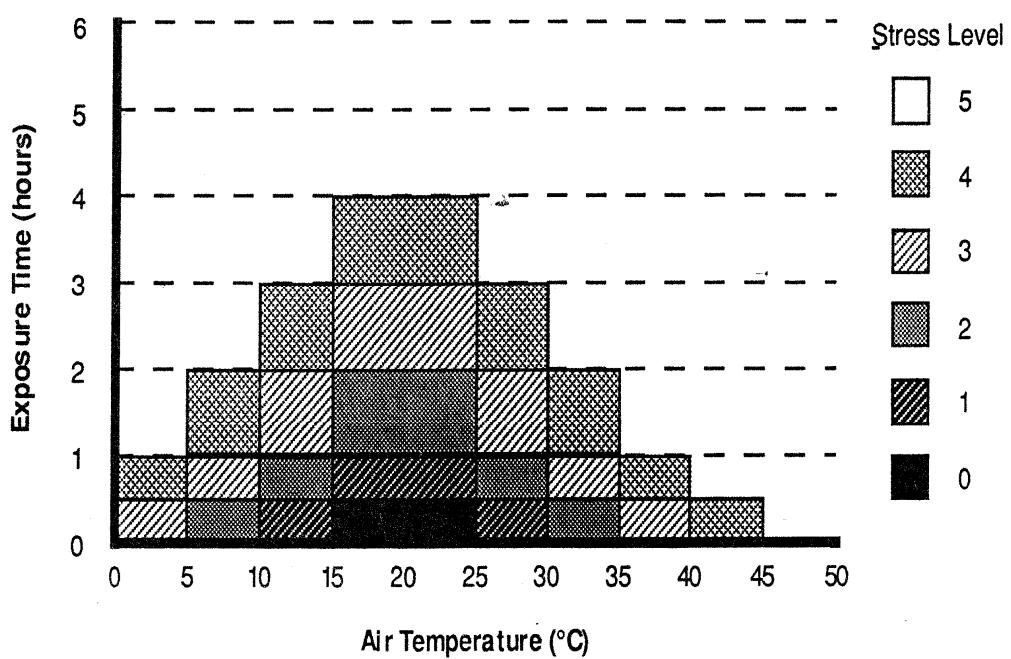
Air; Nude; Light Work



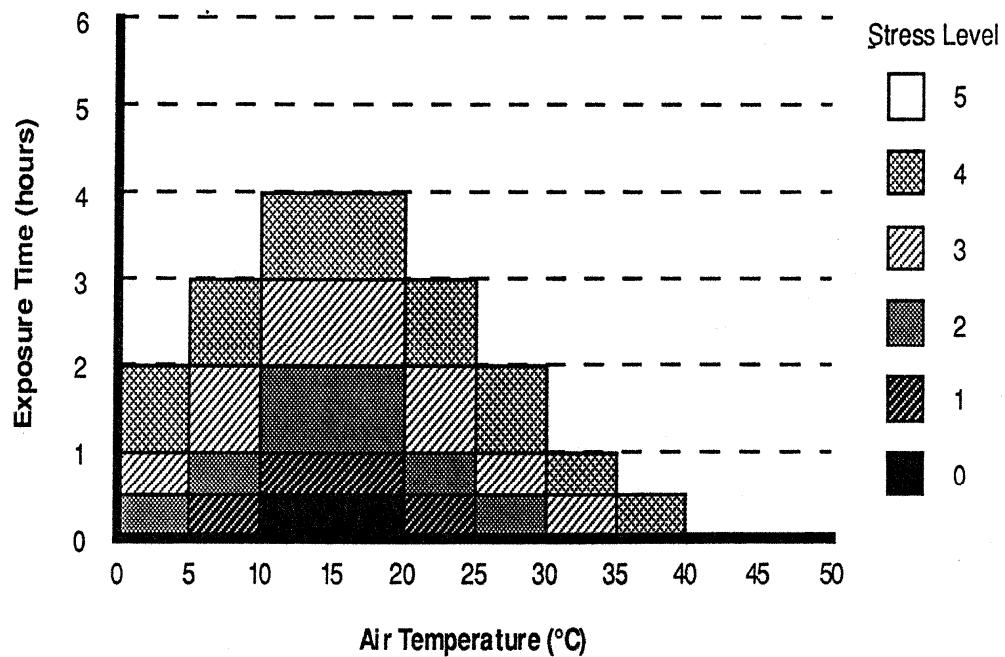
Air; Nude; Heavy Work



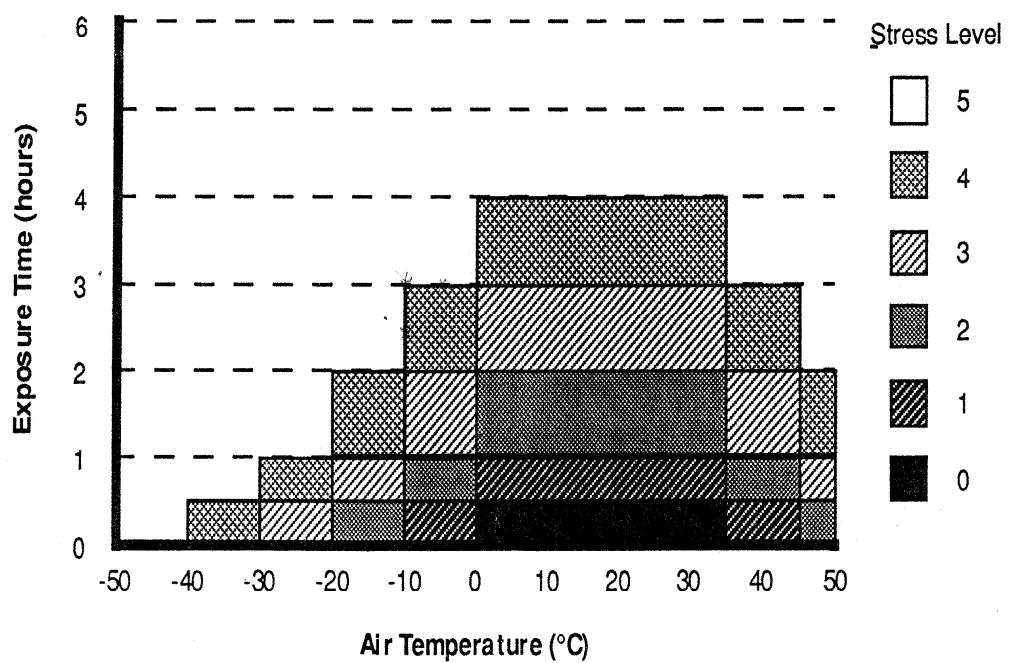
Air; Dressed; Light Work



Air; Dressed; Heavy Work

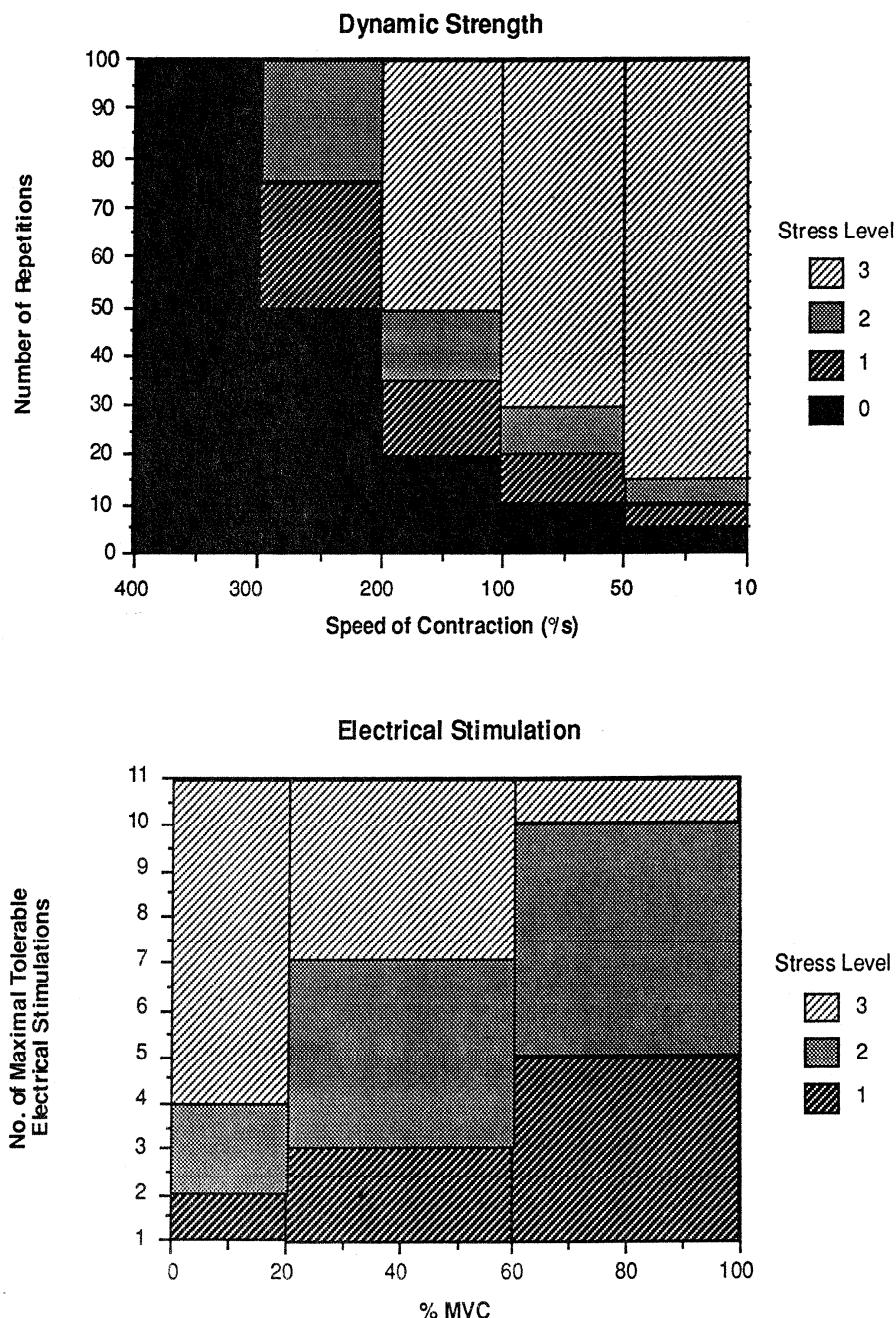


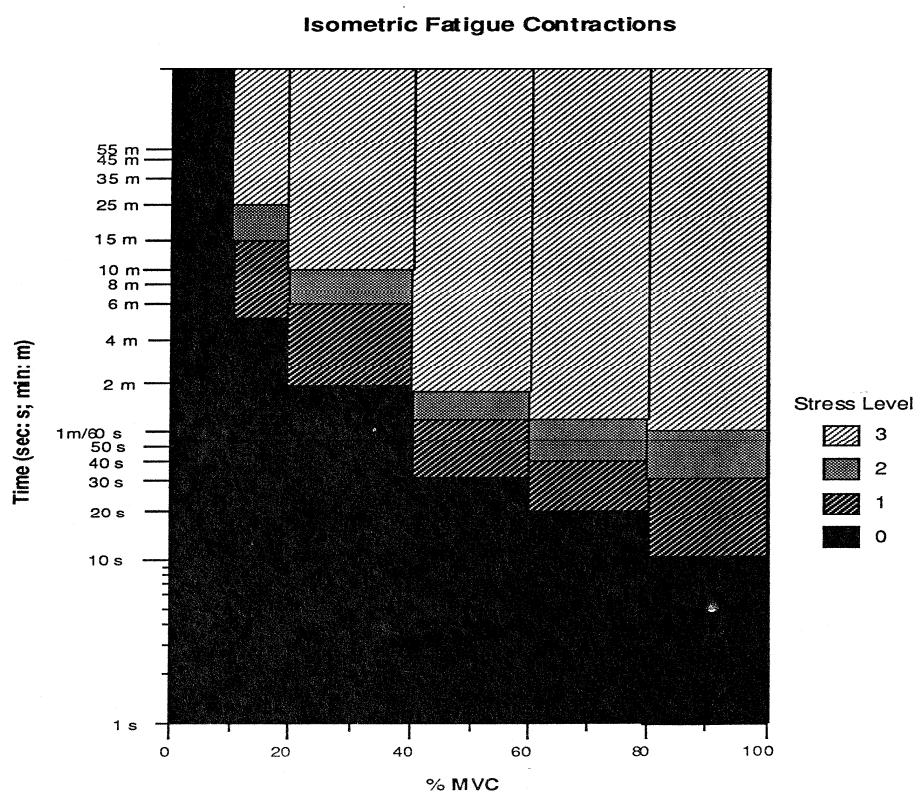
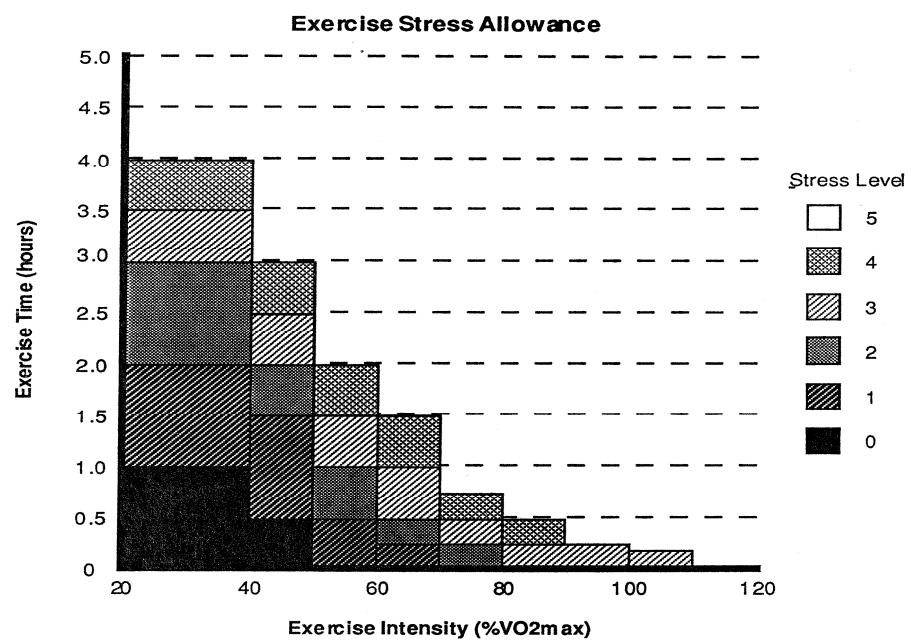
Air; Protected



II. Exercise Stress

Exercise stress has been categorized in the following figures according to time or duration of exercise as well as the percentage of maximal capacity.





III. Blood and Tissue Sampling and Invasive Procedures

Procedure	Number	Stress Level
Finger or ear prick	1-4	1
	5 or more	2
Venipuncture	1	1
	2 or more	2
Venous catheterization	1	2
	each additional	+1
Arterial catheterization	1	5
	each additional	5
Muscle biopsy	1	5
	each additional incision	5
Muscle temperature probe	each	5
Subcutaneous temperature probe	each	2
Rectal probe	each	1
Oesophageal probe	each	2
Drug Ingestion	each	0-3 depending on severity of side effects
Dye dilution	each	0-3 depending on severity of side effects

IV. Other Instrumentation Procedures

Procedure	Stress Level
Thoracic impedance cardiography	1
EEG electrodes or ERP electrode net	1
Infrared temperature probe	0
ECG, skin thermistors and humidity sensors	0
Ingestion of radiopill	0
Use of spirometry equipment	0
Tilt table restrictive posture	1
Wrist actigraphy	0
Use of active heating or cooling vests to prevent the fall or rise of core temperature, respectively	0
Wearing eye tracking or helmet mounted displays	1

V. Additional Environmental Stressors

Environmental Stress	Stress Level
Partial Pressure Breathing	0-5 depending on PPB level and duration
Hyperbaria	0-5 depending on protocol severity
Hypoxia	0-5 depending on protocol severity
Noise	1-3 depending on intensity and duration
Motion Sickness	0-5 depending on protocol severity
+G _z acceleration	0-5 depending on G level and duration

VI. Psychological Stressors

Psychological Stress (when multiple instances of each category of stressors are used, treat as 1 instance of that stressor category)	Stress Level
Questionnaire	0
Questionnaire (content that covers stressful life events)	2
Questionnaire (content that evokes distressing emotions)	2
Interviews (face-to-face)	1
Interviews (content that covers stressful life events)	2

Interviews (content that evokes distressing emotions)	2
Interviews (special populations + content that evokes distressing emotions)	3
Cognitive Tasks	1-2 depending on the task
Socially Induced Stress (group work)	1
Socially Induced Stress (public speaking)	2
Socially Induced Stress (stress/embarrassment regarding content)	2
Sleep Deprivation	0-3 depending on duration
Unrestrained posture	0-2 depending on position
Restrained posture	1-3 depending on position
Confinement with sensory isolation	1-2 depending on duration
Deception (minimal such as false feedback)	1
Deception (higher level with emotional stimuli)	2

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Annex B Examples of Rates of Compensation for Experimental Protocols

1. L-528, Heat Strain While Wearing a new Chemical and Biological Uniform During Mission Oriented Protective Posture (MOPP) 1 and 4.

This protocol involved 7 visits to the laboratory with each visit separated by at least 1 week. Visit 1 involved a medical screening, maximal test of aerobic fitness and underwater weighing for body density. The max test and underwater weighing could be completed in about 1 hour. Each of the other 6 visits involved exercise at 35°C for up to 3 hours while wearing protective clothing, the insertion of an intravenous catheter and a rectal probe. Given subject prep time and showering at the end of the exercise and heat stress, 4 hours were estimated as a requirement for the subject's time. The compensation for these sessions together with the total compensation for the protocol and the average hourly rate of compensation are tabulated below.

Session	Time (h)	Stress Level	Compensation
Aerobic fitness test and underwater weighing	1	3	\$40.60 (\$10 for time and \$30.60 for stress)
Familiarization	4	i. Exercise + heat stress in protective clothing = 5 ii. Venous catheter = 2 iii. Rectal probe = 1 Total = 8	\$121.60 (\$40 for time + \$81.60 for stress)
5 Experimental Sessions separated weekly	Each session = 4	Each session as above for a total of 8 stress units/session	\$121.60/session
Total	25		\$770.20 (\$30.81/hour)

2. L-493, Understanding the Neurochemical and Immunological Mechanisms That Define Limits to Human Physical and Cognitive Function During Acute Heat Stress.

This protocol involved 4 visits to the laboratory with each visit separated by at least 1 week. Visit 1 involved a medical screening, maximal test of aerobic fitness and underwater weighing for body density. The max test and underwater weighing could be completed in about 1 hour. The second visit involved the determination of blood volume by injecting a dye into one arm and sampling blood from the other arm. The procedure required 2 hours to be completed. The third visit was a familiarization visit with exposure to all test conditions but did not require exercise to exhaustion in the heat and was scheduled to be completed in 3 hours whereas 5 hours was scheduled for the last visit because subjects were asked to continue to exercise in the heat until exhaustion. The compensation for these sessions together with the total compensation for the protocol and the average hourly rate of compensation are tabulated below.

Session	Time (h)	Stress Level	Compensation
Aerobic fitness test and underwater weighing	1	3	\$40.60 (\$10 for time and \$30.60 for stress)
Blood Volume	2	i. 2 venous catheters = 3 ii. Injection of dye = 3	\$81.20 (\$20 for time and \$61.20 for stress)
Familiarization	3	i. Exercise + heat stress for 30 min in protective clothing = 3 ii. Venous catheter = 2 iii. Rectal probe = 1 Total = 6	\$91.20 (\$30 for time + \$61.20 for stress)
Experimental Session	5	i. Exercise + heat stress to exhaustion in protective clothing = 5 ii. Venous catheter = 2 iii. Rectal probe = 1 Total = 8	\$131.60 (\$50 for time and \$81.60 for stress)
Total	11		\$344.60 (\$31.33/hour)

3. L-302, Exercise performance 1, 3, and 6 hours after caffeine ingestion.

This protocol involved 8 visits to the laboratory with each visit separated by at least 1 week. Visit 1 involved a medical screening and a maximal test of aerobic fitness. The max test could be completed in about 1 hour. The second visit was a familiarization visit with exposure to all test conditions except for the ingestion of a drug. This visit was expected to be completed in 2 hours. The remaining 6 visits involved exercise to exhaustion 1, 3 or 6 hours after the ingestion of a drug or placebo. Given subject prep time, exercise time and showering after exercise, the total time for each visit was calculated as an additional 2 hours above the 1, 3 or 6 hour period following ingestion of the capsule. The compensation for these sessions together with the total compensation for the protocol and the average hourly rate of compensation are tabulated below.

Session	Time (h)	Stress Levels	Compensation
Aerobic fitness test and underwater weighing	1	3	\$40.60 (\$10 for time and \$30.60 for stress)
Familiarization	2	i. Exercise to exhaustion at 80%max = 4 ii. Venous catheter = 2 Total = 6	\$81.20 (\$20 for time + \$61.20 for stress)
Experimental Session 1	3	i. Exercise to exhaustion at 80%max = 4 ii. Venous catheter = 2 Total = 6	\$91.20 (\$30 for time and \$61.20 for stress)
Experimental Session 2	3	i. Exercise to exhaustion at 80%max = 4 ii. Venous catheter = 2 iii. Drug ingestion = 2 Total = 8	\$111.60 (\$30 for time and \$81.60 for stress)
Experimental Session 3	5	i. Exercise to exhaustion at 80%max = 4 ii. Venous catheter = 2 Total = 6	\$111.20 (\$50 for time and \$61.20 for stress)
Experimental Session 4	5	i. Exercise to exhaustion at 80%max = 4 ii. Venous catheter = 2 iii. Drug ingestion = 2 Total = 8	\$131.60 (\$50 for time and \$81.60 for stress)
Experimental Session 5	8	i. Exercise to exhaustion at 80%max = 4 ii. Venous catheter = 2 Total = 6	\$141.20 (\$80 for time and \$61.20 for stress)
Experimental Session 6	8	i. Exercise to exhaustion at 80%max = 4	\$161.60 (\$80 for time and \$81.60 for stress)

		ii. Venous catheter = 2 iii. Drug ingestion = 2 Total = 8	
Total	35		\$870.20 (\\$24.87/hour)

4. L-238, High altitude man-rating of on-board oxygen generating system (OBOGS) for Hawk Mk 127 aircraft (RAAF lead-in fighter)

This protocol involved subject medical screening (4 h), pressure breathing training (<1 h), and up to 6 altitude test sessions (1 rapid decompression familiarization, 5 experimental) separated by at least 2 days, limited to 2 per week (2 h each including 1 h oxygen pre-breathe). The familiarization altitude profile was a rapid decompression from 24K to 50K ft for <10s while breathing 100% oxygen throughout. Experimental session profiles were: 1) gradual ascents to 35K, 43K and 48K ft for 1 min at each altitude; 2) rapid decompression to 45K ft for 2 min breathing 100% oxygen; 3) repeat of #2 to 50K ft; 4) rapid decompression to 45K ft for 1 min after breathing OBOGS mix; and 5) repeat of #4 to 50K ft. Nominal pressure breathing levels were: 20, 26, 31 and 34 mm Hg at 43K, 45K, 48K and 50K ft, respectively. Sessions 4 and 5 involve hypoxia exposure. The compensation for these sessions together with the total compensation for the protocol and the average hourly rate of compensation are tabulated below.

Session	Time (h)	Stress Level	Compensation
PPB training,	1	PPB = 1	\$20.20 (\$10 for time, \$10.20 for stress)
Familiarization, Experimental Sessions 1 & 3	2	PPB = 2	\$40.40/session (\$20 for time, \$20.40 for stress)
Experimental Session 2	2	iii. PPB = 1	\$30.20 (\$20 for time, \$10.20 for stress)
Experimental Session 4	2	iv. PPB = 1 v. Hypoxia = 2	\$50.60 (\$20 for time, \$30.60 for stress)
Experimental Session 5	2	i. PPB = 2 ii. Hypoxia = 2	\$60.80 (\$20 for time, \$40.80 for stress)
Total	13		\$283.00 (Time average: \$21.77 hour)

5. L-591, Team Communication and Information Sharing

This protocol involves a single session lasting approximately three hours. The task is a collaborative information gathering intelligence and problem solving task. Participants work in teams of either 4 or 17 people. They are required to share discrete bits of information in order to identify the Who, What, When, and Where of an impending terrorist attack. The cognitive components of the task mostly involve deductive logical reasoning. There is a practice session followed by an experimental session. Participants then fill out a questionnaire.

Session	Time (h)	Stress Level	Compensation
Task training,	1	Cognitive Task = 1	\$10.00 (\$10 for time, \$0.0 for stress because cognitive task is multiple instance with experimental session)
Experimental Session	1	Cognitive Task = 1	\$20.20/session (\$10 for time, \$10.20 for stress because this cognitive task is counted as 1 instance)
Questionnaire and debriefing	1	Questionnaire = 0	\$10.00 (\$10 for time, \$0 for stress)
Total	3		\$40.20 (Time average: \$13.40 hour)

List of symbols/abbreviations/acronyms/initialisms

BIO	Biosciences
CBI	Compensation and Benefits Instructions
CF	Canadian Forces
CIHR	Canadian Institute of Health Research
DAOD	Defence Administrative Orders and Directives
DND	Department of National Defence
DRDC	Defence Research and Development Canada
FAA	Financial Administration Act
HREC	Human Research Ethics Committee
IRB	Institute Review Board
NSERC	Natural Science and Engineering Research Council
SSHRC	Social Sciences and Humanities Research Council
TBS	Treasury Board Secretariat

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(U) DRDC Toronto is the Agency's research centre that provides guidance, innovation and knowledge about the human's response to the complex and stressful environments that impact CF members in preparation for, during and following humanitarian, peace-keeping and warfighting operations. The Agency has invested in DRDC Toronto to ensure that we can simulate and study these responses with human experimentation conducted by our scientists during in-house laboratory or field experimentation. Central to this capability is the need to recruit subjects, both military and civilian, that are willing to experience certain degrees of stress that are beyond what they would experience during their normal day, and/or that are willing to commit the time for participation that enables the study to be completed in an appropriate time-frame. New consolidated guidelines were needed to establish consistent and transparent procedures for generating rates of compensation that would still enable free and informed consent to be obtained according to Tri-Council Policy guidelines. The new guidelines are intended to be applicable for all studies involving human subjects at DRDC Toronto and perhaps could be extended, in principle, across the Agency. The report includes the rationale behind the development of these new guidelines together with examples of how to use the spreadsheet that will be available for all scientific and technical staff to apply to their studies.

(U) RDDC Toronto est le centre de recherche de l'Agence qui conseille, fournit les innovations et assure la gestion des données pour tout ce qui touche la réponse humaine aux situations complexes et intenses qui ont des répercussions sur les membres des FC lors de la préparation, de l'exécution ou à la suite de leurs opérations d'aide humanitaire, de maintien de la paix ou de combat. L'Agence a investi dans RDDC Toronto afin de s'assurer que nous pouvons simuler et étudier ces réponses dans le cadre d'expérimentations menées par nos scientifiques, que ce soit sur le terrain ou dans nos laboratoires. Il est essentiel pour cette organisation de pouvoir recruter des sujets ; militaires et civils ; qui acceptent de subir des niveaux de stress supérieurs à ceux qu'ils vivraient au cours d'une journée normale et/ou de les encourager à donner de leur temps pour permettre la conduite de ces études dans un cadre temporel adéquat. De nouvelles lignes de conduite unifiées étaient nécessaires pour élaborer des procédures cohérentes et transparentes qui permettraient d'établir des taux de rémunération qui nous donneraient toujours la possibilité d'obtenir un consentement libre et informé, conformément aux directives de l'Énoncé de politique des trois Conseils. Ces nouvelles lignes de conduite doivent pouvoir être utilisées dans le cadre de toutes les études de RDDC Toronto faisant appel à des sujets humains et pourraient, en principe, être utilisées dans toutes les études de l'Agence. Le présent rapport comprend les explications justifiant l'élaboration de ces nouvelles lignes de conduite et donne également des exemples d'utilisation de la feuille de calcul. Celle-ci pourra être utilisée par tout le personnel scientifique et technique dans le cadre de ses études.

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(U) human ethics, stress allowances, Tri-Council policy, informed consent

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